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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/752,438	01/05/2004	Wolfgang Fitz	2960/118	3735
75059 7590 06/28/2010 Sunstein Kann Murphy & Timbers LLP 125 SUMMER STREET BOSTON, MA 02110-1618				
EXAMINER				
STEWART, JASON-DENNIS NEILKEN				
ART UNIT		PAPER NUMBER		
3738				
MAIL DATE		DELIVERY MODE		
06/28/2010		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/752,438

Applicant(s)

FITZ ET AL.

Examiner

JASON-DENNIS STEWART

Art Unit

3738

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 April 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-17, 19-29, 32-38, 40, 42-46 and 49-56 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-17, 19-29, 32-38, 40, 42-46 and 49-56 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date See Continuation Sheet
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :16 November 2009, 25 February 2010, 04 March 2010, 09 April 2010.

DETAILED ACTION

The following is a Final Office action in response to communications received on 04/12/10. Claims 1, 16, 17, 27, 28, 29, 32, 34-38, 40, and 42-46 have been amended. Claims 2, 18, 30, 31, 39, 41, 47, and 48 have been cancelled. Claims 49-56 have been added. Therefore, claims 1, 3-17, 19-29, 32-38, 40, 42-46, and 49-56 are currently pending and addressed below.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 50 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim is rendered indefinite because of the lack of clarity of the claim language. The claim was examined as best understood by the Examiner, but grammatical correction is requested.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1, 3-5, 8, 11-14, 16, 17, 19-26, 28, 29, 34-38, 40, 42-46, and 49-56 are rejected under 35 U.S.C. 102(e) as being anticipated by Carignan et al. 6,712,856.
5. Carignan discloses a replacement device for resurfacing a femur that has joint facing and bone-facing sides. The bone-facing side abuts at least a portion of the femoral condyles and the trochlea (Figs. 3-9) (Claims 1 and 28). The implant is designed to rebuild a cartilage defect in a patient and to match the uncut femoral bone of a patient with a custom fit. The condylar articular surface of the implant (joint facing side) is curved and substantially replicates the curvature of an uncut femoral condyle (Fig. 3). The thickness of the device may vary approximately between 2 mm and 6 mm, depending of the thickness of the patient's original cartilage (col. 7, ll. 9-22). The device is fixed to the distal femur with anchoring pins (Fig. 1). The device is also designed to maintain the "normal kinematics of the joint" i.e. normal joint motion (abstract). It should be noted that the limitation "...a planar surface to abut a bone cut surface..." is a functional limitation and holds limited patentable weight. The bone facing implant of Carignan is fully capable of abutting a bone cut surface.
6. Regarding Claims 20 and 21, they do not further limit the structure of the claimed device and, as a result, hold no patentable weight.

7. Regarding Claim 51, the term "portion" is broad and does not disclose any particular element or section of the device. Giving the term its broadest reasonable interpretation, the implant may have any number of condylar "portions".

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 6, 7, 9, 10, 32, and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carignan et al. 6,712,856 in view of Fell 2003/0060882.

10. Carignan discloses the invention as claimed and as discussed above. However, Carignan does not disclose an offset thickness.

Fell '882 discloses a metal knee prosthesis (paragraph 74) with biologically active surfaces (paragraph 74) and an offset defined by a ratio (paragraph 28, fig. 3).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Carignan with the offset of Fell '882 in order to restore normal joint alignment without requiring any bone resection as taught by Fell '882 (paragraph 17).

11. Claims 15 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carignan et al. 6,712,856 in view of Rolston 2004/016730.

12. Carignan discloses the invention as claimed and as discussed above. However, Carignan does not disclose a second implant component that covers a portion of the patellar surface. Rolston discloses a second component 58 that has a first surface that engages the femur mating surface of the patella and a second surface that engages the patella (fig. 6). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Carignan with the patellar implant of Rolston in order to remedy a patella that is also diseased as taught by Rolston (paragraph 5).

Response to Arguments

13. Applicant's arguments filed 04/12/10 have been fully considered but they are not persuasive. The Applicant argues that Carignan does not disclose an implant having a condylar bone facing implant surface that includes, at least in part, a planar surface to abut a patient's condyle. The Applicant also recites a passage that the Applicant believes proves that Carignan teaches away from abutting against a bone cut surface. The Examiner respectfully disagrees. It should be noted that the bone facing surface of Carignan is fully capable of abutting a bone cut surface. Furthermore, Carignan discloses that there is "*almost* no removal of the original bone" (col. 7, ll. 2-4), meaning the original bone may be cut to some degree. Therefore, Carignan does not teach away from cutting the bone.

Conclusion

14. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JASON-DENNIS STEWART whose telephone number is (571)270-3080. The examiner can normally be reached on M-F (alt Fridays off) 7:30-5:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571)272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/William H. Matthews/
Primary Examiner, Art Unit 3774

/Jason-Dennis Stewart/
Examiner, Art Unit 3738